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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,501	11/26/2003	Richard L. Veech	604-701	6205
23117	7590	04/08/2005	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,501	<b>Applicant(s)</b> VEECH, RICHARD L.	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/26/2003</u> . | 6) <input type="checkbox"/> Other: ____.  |

**CLAIMS 1-31 ARE PRESENTED FOR EXAMINATION**

Applicant's Preliminary Amendment and Information Disclosure Statement filed November 26, 2003 have been received and entered into the application. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, the Examiner has considered the cited references.

***Specification***

The specification is objected to because the current status of two of the parent applications need to be updated. In particular, in the above referenced amendment to the specification, the status of Serial Nos. 10/207,114 and 09/433,716 should be changed from "pending" to ---now abandoned---.

***Claim Objection***

Claim 21 is objected to because at line 21, line 3 the term "prom" should read ---from---.

***Claim Rejection - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claims is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what

Art Unit: 1614

applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the specification meets the criteria of 35 U.S.C. 112, first paragraph with respect to the claimed invention.” (MPEP 2173).

The term "about" in the expressions "about 0.01 to 1400 millimoles per liter" (claim 1); "about 1 to 1000 millimoles per liter" (claim 3); "about 20:1 to 1:1" (claim 13); "about 6:1 to 0.5:1" (claim 13); "about 6 to 8.4" (claim 18); "about 0.1 to 2400 mM" (claims 19 and 20); "about 5 to 8.2" (claims 19, 20 and 23-26); "about 0.1 to 55 mM" (claims 21-24); "about 6.0 to 7.5" (claim 21 and 22); "about 250 to 600 mOs/l" (claim 23); "about 20 to 55 mM" (claim 25-29); "about 260 to 540 mOsmoles/Liter" (claim 25); "about 250 to 550 mOsmoles/Liter" (claims 26-29); "about ½ to four hours" (claim 27); "about 5.5 to 7.5" (claims 27-29); "about 20 to 55 mM" (claim 29); and "about 240 to 2400 mOsmoles per liter" (claim 31) is a relative term which renders the claim indefinite. The expression "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "about" is not defined by Applicant, such would invite subjective interpretations of whether or not a particular quantity, concentration or time period is included by or excluded from the present claims. Therefore, it is the Examiner's position that the public would not be informed of the boundaries of what constitutes infringement of the present claims and thus the claims fail to meet either the tenor or express requirements of 35 U.S.C. § 112, second paragraph and are properly rejected.

***Double Patenting***

***I*** Claims 1-18 and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 18 of U.S. Patent No. 5,100,677, cited by Applicant.

Although the conflicting claims are not identical, they are not patentably distinct from the above claims and the presently claimed subject matter would have been obvious in view of the patented claims. In particular, while the specifically claimed ingredient amounts/concentrations are not exactly recited in the patented claims, the ingredient amounts presently claimed are clearly within the ranges present in the patented claims. Also, because the solute concentrations as presently claimed are within those concentration ranges of the patented claims, it is believed that the claimed osmolarity range would also be encompassed (i.e., present claim 31).

***II*** Claim 20, 22, 24-26 and 28. are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,020,007, cited by Applicant.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredient amounts and pH ranges presently claimed are clearly within the ranges present in the patented claims and thus would have been obvious to one of ordinary skill in the art. Also, the present recitations of an intended use does not impart any physical feature to the presently claimed compositions that is not present in the patented composition and thus fails to serve as a patentable distinction.

***III*** Claims 21 and 29 are rejected under the judicially created doctrine of obviousness-type

Art Unit: 1614

double patenting as being unpatentable over claims 1, 3, 11, 18 and 21-23 of U.S. Patent No. 5,100,677, cited by Applicants, and relied on above.


Although the conflicting claims are not identical, they are not patentably distinct each other because the ingredient amounts/proportions presently claimed are clearly within the range present in the patented claims and thus, the presently claimed subject matter would have been obvious to one of ordinary skill in the art. Also, the objective of the patented claims, i.e., accomplishing fluid therapy, is unrestricted and thus appears broad enough to encompass the presently claimed objective of accomplishing rehydration, electrolyte replacement and nutrition.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Raymond J Henley III  
Primary Examiner  
Art Unit 1614

April 6, 2005